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10/510,694	10/08/2004	Kenji Mori	MUR-043-USA-PCT	4087
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EXAMINER HOLLOWAY, IAN KNOBEL				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,694

Applicant(s)

MORI ET AL.

Examiner

IAN K. HOLLOWAY

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed (4/28/2008). Claim 2 has been canceled without prejudice. Claims 1 and 3-20 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 3-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 12 are rejected under 35 U.S.C. 102(3) as being unpatentable over **Crawford et al. (US Patent 6662044)**.

Regarding **Claims 1 and 2**, **Crawford et al.** discloses the use of two different electric field applying means, iontophoresis and electroporation, (Column 1, lines 22-24) to distribute therapeutic agents (Column 4, lines 23-24). To transmit insulin lispro (the construction of **Crawford** is capable of this)

Regarding **Claim 12**, the device of **Crawford et al.** discloses the use of applying a patch to skin. (Column 3, line 40)

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 3, 4, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crawford et al.** in further view of **Mori et al.** (US PgPub 2001/0039393)

Regarding **Claim 3**, the device of **Crawford et al.** discloses the invention claimed as stated above except for the range of current used by the electrodes.

However, **Mori et al.** teaches a similar electroporation device where the current range used is .01 to 10 mA (Claim 40).

The device of **Crawford et al.** discloses the claimed invention except for the optimum current range. It would have been obvious to one of ordinary skill in the art at the time the invention was made to test within all reasonable ranges, including those set forth by **Mori et al.**, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **Claim 4**, the device of **Crawford et al.** fails to disclose the range of voltage used by the electrodes.

However, **Mori et al.** teaches a similar electroporation device where the Voltage range used is .1 to 50 V (Claim 42)

The device of **Crawford et al.** discloses the claimed invention except for the optimum voltage range.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test within all reasonable ranges, including those set forth by **Mori et al.**, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **Claim 15**, the device of **Crawford et al.** discloses the use of combination electroporation (315) and iontophoresis (302) electrodes that are disposed on a membrane. The system also utilizes a drug reservoir and insulin lispro.

The device of **Crawford et al.** fails to disclose the overall design of the electrode.

However, **Mori et al.** teaches the overall design of the electrode, including having a backing; an iontophoresis electrode disposed on the backing; and the presence of a membrane (Fig. 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to rearrange the parts of **Crawford et al.** as taught by **Mori et al.**, since such modification would result in a easier to build electrode.

Because both **Crawford et al.** and **Mori et al.** teach electrodes for use with iontophoresis and electroporation, it would have been obvious to one skilled in the art to substitute one electrode geometry for the other to achieve the predictable result of a usable electrode.

Regarding **Claims 16 and 17**, the device of **Crawford et al.** discloses the invention as claimed above except for the presence and porosity of the membrane.

However, **Mori et al.** teaches the presence of a membrane. The membrane has a pore size of about 0.01 μm to 10 μm . (Page 5, Claim 2)

The device of **Crawford et al.** discloses the claimed invention except for the presence of the membrane. **Mori et al.** teaches that it is known to use a membrane with electrodes. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a membrane as taught by **Mori et al.**, since such modification would make the device more effective, since it would be agent permeable (Paragraph 19, **Mori**).

Since the marketplace reflects the reality that applying membranes to electrodes is commonplace, it would have been obvious to one of ordinary skill in the art of

electroporation and iontophoresis as shown in **Crawford et al.** with the use of a membrane as shown in **Mori et al.**, in order to gain the commonly understood benefits of such adaptation, such as a more effective electrode.

In addition, **Crawford et al.** discloses the claimed invention except for the optimum porosity of the membrane.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test within all reasonable ranges, including those set forth by **Mori et al.**, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **Claim 20**, the device of **Crawford et al.** and **Mori et al.** discloses that the number of electrodes utilized in **Crawford et al.**'s disclosure is not limited; therefore, more than one contact point could be used.

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crawford et al.** in view of **Jacobsen et al.** (US patent 4416274)

Regarding **Claims 5** and **6**, the device of **Crawford et al.** discloses the invention as claimed above except for the use of a hydrophilic matrix.

However, **Jacobsen** teaches the use of a hydrophilic matrix used in iontophoresis. The matrix can be constructed from many different materials, including polyvinyl alcohol. (Column 3, lines 33-37)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose to make the matrix out of hydrophilic material, Since it

has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

6. Claims 7-10 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over **Crawford et al.** in view of **Mori et al.**

Regarding **Claims 7 and 9**, the device of **Crawford et al.** discloses the invention as claimed above except for the use of a membrane.

However, **Mori et al.** teaches the presence of a membrane. The membrane has a pore size of about 0.01 μm to 10 μm . (Page 5, Claim 2)

The device of **Crawford et al.** discloses the claimed invention except for the presence of the membrane. **Mori et al.** teaches that it is known to use a membrane with electrodes. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a membrane as taught by **Mori et al.**, since such modification would make the device more effective.

Since the marketplace reflects the reality that applying membranes to electrodes is commonplace, it would have been obvious to one of ordinary skill in the art of electroporation and iontophoresis as shown in **Crawford et al.** with the use of a membrane as shown in **Mori et al.**, in order to gain the commonly understood benefits of such adaptation, such as a more effective electrode.

Regarding **Claim 8**, the device of **Crawford et al.** discloses the presence of electroporation electrodes (Fig. 3, electrode gaps are formed for electroporation, **Crawford**) on a membrane. (Column 9, lines 62-67, **Crawford**)

Regarding **Claim 10**, the device of **Crawford et al.** and **Mori et al.** discloses the invention claimed above except for the membrane's ability to retain insulin lispro.

However, one of ordinary skill in the art at the time of the invention would know to allow the membrane to retain whatever material it is supposed to have permeability to.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make it so the membrane was not impermeable to the material it is supposed to carry since it was known in the art that any material that allows a substance to pass through it, must also be able to retain it for some amount time.

Regarding **Claim 18**, **Crawford et al.** discloses the use of combination electroporation (315) and iontophoresis (302) electrodes that are disposed on a membrane (Column 1, lines 22-24).

Crawford et al. fails to disclose many other aspects of the invention.

However, **Mori et al.** teaches a backing, an iontophoresis electrode disposed on the backing, a hydrophilic matrix base disposed on the iontophoresis electrode, a liner disposed on the hydrophilic matrix base, a retaining membrane which is disposed on the liner (Fig. 3).

7. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crawford et al.** in view of **Mori et al.** in further view of **Murdock (US PgPub 2002/0058903)**.

Regarding **Claims 11 and 19**, the device of **Crawford et al.** as modified by **Mori et al** discloses the invention claimed above except for the storage of lispro in the dry state.

However, **Murdock** teaches the use of anhydrous, dry, drug reservoirs used in iontophoresis. (Abstract)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to include an anhydrous drug reservoir as taught by **Murdock**, since such modification would make the electrode longer lasting. Thus, it would have been obvious to one of ordinary skill in the art to apply anhydrous reservoirs as taught in **Murdock**, to improve the electrode of **Crawford et al.** for the predictable result of creating an electrode with a longer shelf life (Paragraph 21, **Murdock**).

8. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crawford et al.** in view of **Miller et al. (US Patent 7137975)**

Regarding **Claims 13**, the device of **Crawford et al.** discloses an electroporation-iontophoresis (**Crawford**) formulation containing insulin lispro.

The device of **Crawford et al.** fails to disclose the counter electrode and the power supply.

However, **Miller et al.** teaches the use of an electrode and a counter electrode (202, 204) and a power supply (206) (Figure 9). It further teaches two attachment points on the power supply (206, figure 9)

The device of **Crawford et al.** discloses the claimed invention except for the counter electrodes and their attachment points on a power supply. **Miller et al.** teaches that it is known to use multiple electrodes and a power supply for iontophoresis. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to include the power supply as part of the system as taught by **Miller et al.**,

since such modification would make the device usable. Thus, it would have been obvious to one having ordinary skill in the art to include the power supply taught by **Miller et al.** in view of the electrodes shown by **Crawford et al.**, since the electrode design is in no way dependent on which power supply is utilized. The electrodes could be used in combination with **Miller et al.**'s power supply to achieve the predictable result of performing electrophoresis and iontophoresis.

Regarding **Claim 14**, the device of **Crawford et al.** fails to disclose a connecting port used for iontophoresis and a connecting port used for electroporation.

However, **Miller et al.** discloses a connecting port used for iontophoresis and a connecting port used for electroporation (206, Fig. 9).

it would have been obvious to one having ordinary skill in the art to include a connecting port used for iontophoresis and a connecting port used for electroporation taught by **Miller et al.** in view of the electrodes shown by **Crawford et al.**, since the combination with **Miller et al.**'s connecting ports will achieve the predictable result of performing electrophoresis and iontophoresis.

Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive.

Response to Arguments

Applicant states, that Insulin lispro was not shown to be a reasonable material to use with electrotransport and that the **crawford** reference does not disclose the use of transporting insulin. Examiner agrees with that statement, however, **Crawford** discloses a device which very closely resembles applicant's device, by applicant's own

admission, Crawford discloses a sundry of medications able to be delivered using the combination of iontophoresis and electroporation. The range in size of the particles for transport disclosed by Crawford is wide, and although insulin lispro is not specifically disclosed, there is no suggestion that it would be incapable of transporting that molecule. Therefore, the original rejection is maintained.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ian K Holloway/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763